REMARKS

Status of the Claims

The pending office action addresses claims 1, 3, 5, 6 and 10-31. All claims stand rejected with claim 1 being the only independent claim. By this response, Applicants have amended no. Upon entry of this amendment, claims 1, 3, 5-6 and 10-31 will remain pending in the application, and Applicant respectfully requests reconsideration.

In an effort to simplify the issues, Applicant focuses in this response on claims 1 and 30.

Claim Rejections - 35 USC §102

The Examiner has rejected claims 1, 3, 5, 6, 13, 14, 19, 28 and 30 under 35 USC 102(e) as being anticipated by Schafer (U.S. 6,143,032). Specifically, the Examiner states:

> Fig. 3 shows a unitary body that is banana-shaped as viewed from above. Fig.2 illustrates the body has openings evenly spaced about the circumference. Schafer discloses the body has a continuous front arc and a continuous back arc with two radiuses of curvature either equal or different, col. 2, lines 26-32. Schafer also discloses the implant body can be made of a metal or polymer, col. 3, lines 14,15. According to Figs. 1 and 3, it can be construed that the width is greater than the length. Regarding Claim 30 is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al. It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

Applicants fully addressed these rejections in the previous Amendment. Nevertheless, the Examiner provided the following Response to Arguments:

> Applicant's arguments filed 9/4/07 have been fully considered but they are not persuasive. Applicant argues that the spinal prosthesis disclosed by Schafer et al. is not banana-shaped, but kidney shaped. First the Examiner would like to point out that all bananas are not the same shape since there are numerous types of bananas that vary in size, shape and color. There are dwarf and red bananas that are short. Then there are Cavendish bananas that are longer and yellow. Then there is the plantain banana that

> is long and greenish with a more elongate appearance and less *of* curved look to them than the yellow Cavendish type. Thus, there is not an exact or specific shape that is implied, just because Applicant's claim recites "banana-shaped". Applicant also alleges the Schafer device looks like a cage similar to a device invented by Harms which the Applicant says is kidney-shaped and not banana-shaped. Comparing the prior art with other prior art is irrelevant and thus the Examiner would like to illustrate a comparison of Applicant's device with that of Schafer's as shown below.
>
> The figure on the left is the claimed invention and the figure on the right is the prior art device disclosed by Schafer. One of ordinary skill would clearly state they look identical. Applicant also argues the Examiner has not shown where the different radius of curvature is disclosed. However, it appears the Applicant's representative has totally ignored or overlooked that the Examiner referred to col. 2, lines 29-31 in the office action where two different radii are disclosed by Schafer. Applicant again compares the prior art device of Harms with the prior art Schafer implant in addressing the rejection of claim 30 made by the Examiner. The Examiner would like to note that a comparison of prior art not relied on is a moot point and the Examiner will not entertain these issues.
>
> Applicant argues that the dimensions of Schafer's device cannot be modified as claimed. However, clearly one of ordinary skill in the art is capable of modifying an implant's size to accommodate the different anatomical dimensions found in patients.

While Applicant very much appreciates the Examiner's humor, as well as his encyclopedic and downright mouth-watering knowledge of various bananas – both the rejection and the Response miss the point: (1) banana-shaped and kidney-shaped are different; and (2) there is still not stated any reason to design a prosthesis having a width that is at least 2.4 times greater than the length – and in fact, the prior art teaches away from such a design.

Applicant is entitled to employ terminology that most suitably describes his invention, and may employ drawings to facilitate clarity in their description. Item 15 of the figures plainly shows an embodiment of Applicant's claimed intervertebral prosthesis that is of a banana-shape. Applicant has characterized that embodiment in the claims as a "banana-shape." Moreover, Applicant has specifically contrasted his "banana-shaped" intervertebral prosthesis with prior art intervertebral prostheses and has described the advantages that come from shaping the prosthesis in the manner that the manner that the Applicant has shaped it.

Everyone, including the person of ordinary skill in the art, knows what a "banana" is. Webster's Third New International Dictionary (P. Gove, ed., Merriam-Webster 1986), a dictionary that has been cited by the Federal Circuit Court of Appeals in patent cases more than 100 times, defines "banana" as follows: "the ***elongated often curved and usu. tapering*** fruit of the banana plant having soft pulpy flesh and a rind that is usu. yellow or orange-colored when ripe and dark brown to black at full maturity" (emphasis added) (p. 169). It should come as no surprise that the definition of banana begins with its shape, as bananas have a distinctive and well understood shape. It goes without saying, as the Examiner notes, that bananas come in different sizes and colors – but size and color is irrelevant to the claim term "banana-shaped." It is also true that there is some variation in the shape of bananas, but this variation is quite limited, and in every case, the shape of the banana is distinct from the shape of a kidney – a point that the Examiner never addresses.

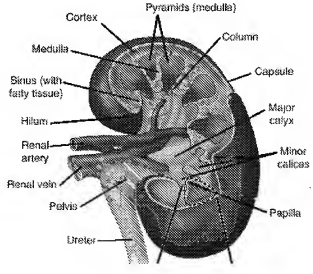
According to the Office Action, "Fig. 3 [of Schafer] shows a unitary body that is banana-shaped as viewed from above." Figure 3 does not show such a shape and Schafer expressly states otherwise. Rather than being banana-shaped, the device of Schafer, and particularly as disclosed in Figure 3, is kidney-shaped:

> In a preferred embodiment, the side wall of the hollow body is curved in a ***kidney-shaped*** fashion . . . so that the intervertebral implant can ***best match the shape of the vertebral bodies.*** . . . FIGS. 1 and 3 ***clearly show that the intervertebral implant 1 is approximately kidney-shaped.*** [Column 1, lines 25-45 and Column 2, lines 58-59.]

The shape of a kidney is also well known, including to those of ordinary skill in the art. Dorland's Illustrated Medical Dictionary defines "kidney" as follows (emphasis added):

> kidney (kid·ney) (kid´ne) [L. ren; Gr. nephros] either of the two organs in the lumbar region that filter the blood, excreting the end-products of body metabolism in the form of urine, and regulating the concentrations of hydrogen, sodium, potassium, phosphate, and other ions in the extracellular fluid. Called also ren [TA]. Each human kidney is ***about 11 cm long, 5-7.5 cm wide,*** and 2.5 cm thick, and weighs from 120-160 gm. ***The kidney is of characteristic shape,*** with a notch known as the hilum on its inner, concave

border; renal vessels and nerves and the ureter pass through it, and it communicates with the cavity or sinus of the kidney. The kidney consists of a cortex (see renal cortex, under cortex) and a medulla (see renal medulla, under medulla). The medullary substance forms pyramids, whose bases are in the cortex and whose apices, the renal papillae, project into the calices of the kidney. The renal pyramids number from 10 to 15. The parenchyma of each kidney is composed of about one million renal tubules (nephrons, the functional unit of the kidney), held together by a little connective tissue. Each tubule begins blindly in a renal corpuscle, consisting of a glomerulus and the surrounding glomerular capsule, situated within the cortex. After a neck or constriction below the capsule, it becomes the proximal convoluted tubule, then Henle's loop, then the distal convoluted tubule, the connecting tubule, and finally the straight collecting tubule, which opens at the apex of a renal papilla. The straight collecting tubules converge as they descend, forming groups in the center, known as medullary rays.



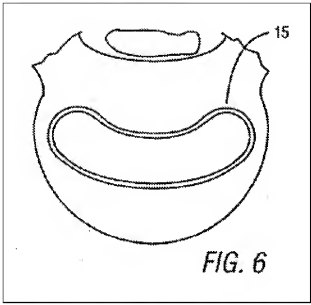
The kidney thus has a characteristic shape with a width to length ratio (as those dimensions are defined in the application) of 11/7.5 to 11/5 – or about 1.5 to 2.2. The characteristic shape of a kidney is thus not only qualitatively distinguished from the more elongate banana shape, but the ratio of width to length is quantitatively outside of the range specified in claim 30 of greater than 2.4.

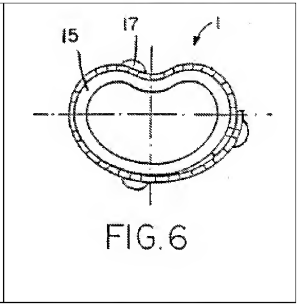
Schafer expressly defines the shape of its prosthesis as "kidney shaped," and further states that it is kidney shaped for a reason – that is, it fits better to the vertebrae if it is kidney shaped. Indeed, there is a long history of kidney-shaped spinal prostheses that are designed to match the shape of the vertebral bodies they contact. Applicant's claimed prosthesis is different precisely because it is banana-shaped. In particular, the banana-shaped prosthesis of the claims is thinner than the fatter kidney-shape of the prior art. It is this difference in shape that provides the benefits of the claimed invention (namely, that it can easily be inserted from key approaches) as quoted extensively from the specification in the prior response and below at pages 13 to 14.

The Examiner strenuously responded to Applicant's reference to the Harms patent (US 4,820,305) that had previously been relied upon to reject the claims. In fact, the Harms reference is highly relevant. Harms expressly teaches that:

> Preferably the cross-section is chosen as a function of the cross-section of the parts to be connected. For connection of the vertebrae/body in the lumbal region the member preferably comprises a kidney-shaped cross-section. . . Column 3, lines 20-24.

Like Schafer, Harms shows a kidney-shaped prosthesis. The clearest way to visualize why the prior art (both Schafer and Harms) use a kidney-shaped prosthesis is to compare the banana-shaped prosthesis of Figure 6 of the present application (in reference to the vertebral body) to Figure 6 of Harms, which shows a kidney-shaped prosthesis.:





It is readily apparent that the kidney-shaped prosthesis (here illustrated from Harms) matches the shape of the prosthesis quite closely (which is why both Schafer and Harms prefer this shape, with Schafer saying multiple times as "kidney-shaped" and is said to be kidney-shaped in order to "best match the shape of the vertebral bodies"). Meanwhile, Applicant's preferred "banana-shaped" prosthesis is elongate and curved – consistent with the definition of banana. The kidney shapes are much fatter and will fit within the intervertebral space in a very different way.

Finally, the Examiner provides a top view of Applicant's banana-shaped prosthesis, next an isometric view of Schafer's kidney-shaped prosthesis, and states that "[o]ne of ordinary skill would clearly state they look identical." One of ordinary skill would not attempt to determine if the shapes were the same by comparing different views. Looking at the top view of Schafer, Schafer is clearly fatter and less curved – that is, it is more kidney-shaped, as Schafer says it is.

There is no doubt that Schafer does not disclose a "banana-shaped" prosthesis – it discloses a "kidney-shaped" prosthesis that is different from "banana-shaped." Accordingly, Schafer cannot anticipate claim 1.

The Examiner rejects claim 30 as anticipated without ever providing support for the recitation of claim 30 that "the banana-shape of the unitary body includes a width and length

wherein the width is at least 2.4 times greater than the length." There being no such disclosure in Schafer, claim 30 likewise cannot be anticipated by Schafer.

The Examiner apparently appreciates this lack of disclosure in Schafer and states that "[r]egarding Claim 30 [sic] is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al." In order to make out an obvious rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art (a kidney-shaped prosthesis) to the claims (a banana-shaped prosthesis wherein the banana-shape of the unitary body includes a width and length wherein the width is at least 2.4 times greater than the length). *See In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds ***cannot be sustained by mere conclusory statements***; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness") (emphasis added). Without such rational underpinning, the Examiner easily fall prey to improper hindsight reasoning:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *See Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'".) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, the Examiner's rational underpinning for the obviousness of claim 30 is that:

> It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

These claims have nothing to do with size and have no size limitations whatsoever. These claims are about shape. The key feature of the ***claimed shape makes the prosthesis different from the patient's physiology.*** If the Examiner's hypothetical surgeon were a person of ordinary skill in the art, that surgeon would pick a size and shape of prosthesis that matches

the size and shape of the patient's vertebral body – because that is what all of the art of record teaches. Claim 30 expressly teaches a different shape that does not match up with the patient's vertebral body because Applicant has discovered that this shape has other over-riding benefits – and these benefits are clearly stated in the application. Namely, the presently claimed shape provides for safer and more convenient implantation from a variety of approaches in a single step. For example, the specification provides:

> FIG. 6 shows the banana-shaped cage of the invention 15 within the disc space, as view[ed] from above. Note that the cage 15 is curved so that it mirrors the natural radius of curvature of the anterior and posterior curves of the vertebral bodies. [Page 7, lines 11-13.]

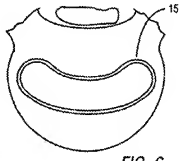


FIG. 6

> The ***unitary cage 15 can be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, tranforaminal interbody fusion or TLIF).*** The cage is curved so that it mirrors the natural radius or curvature of the anterior and posterior curves of the vertebral bodies. ***It can be placed from an anterior position or posterolateral position after standard discectomy.*** [Page 7, lines 3-8.]

* * *

> FIG. 2 shows the implant device of the invention, designated generally as 15. In the preferred embodiment illustrated, ***the unitary body 15 is a cage configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure.***

Further, Applicant has explicitly described the advantages of the claimed prosthesis have the recited shape relative to prior art systems. Specifically, as stated at page 9, lines 14 through 17:

> An invention has been provided with several advantages. The ***unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space*** and is mechanically more stable than the previous two component systems currently in use.

Applicant has developed a shape that provides these benefits despite the express teaching in the very prior art reference relied upon by the Examiner not to shape the prosthesis this way. The Examiner's *ex post facto* reasoning would frustrate the very purpose of the kidney shape in the prior art – ***Schafer teaches to make the prosthesis look like the vertebral body while the supposedly obvious modification would make the prosthesis look less like the vertebral body***. As one would expect, the law of obviousness does not permit this approach. According to MPEP § 2143.01(V), "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the propose modification" (citation omitted). Further, in accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious" (citation omitted). Here, the issue is shape, and the prior art teaches that the prosthesis should take the shape of the vertebral body. The modification would make the prosthesis look less like the vertebral body. There is no reasoning for doing to Schafer the opposite of what Schafer teaches.

CONCLUSION

In view of the above, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance and Applicants urge the Examiner to move this case to issuance.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director, however, is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-706.

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Respectfully submitted,

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